



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2004-N-0252]

Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Color Additive Certification Requests and Recordkeeping--21 CFR Part 80 (OMB Control
Number 0910-0216)--Extension

We have regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are described in 21 CFR part 80. In the certification procedure, a representative sample of a new batch of color additive, accompanied by a “request for certification” that provides information about the batch, must be submitted to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch. We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification.

Under § 80.21, a request for certification must include: Name of color additive, manufacturer’s batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. Under § 80.22, a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show: Name of color additive,

manufacturer's batch number and quantity, and name and address of person requesting certification. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all the color additive.

The purpose for collecting this information is to help us assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been denied certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-denied color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. We check storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its

listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
80.21; Request for Certification	35	199	6,965	0.17	1,184
80.22; Sample to accompany request	35	199	6,965	0.05	348
Total				0.22	1,532

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 – Estimated Recordkeeping Burden¹

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
80.39; Record of Distribution	35	199	6,965	0.25	1,741

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate on our review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 3,273 hours. The estimated reporting burden for this information collection is 1,532 hours and the estimated recordkeeping burden for this information collection is 1,741 hours. From FY 2011 to FY 2013, we processed an average of 6,954 responses (requests for certification of batches of color additives) per year. There were 35 different respondents, corresponding to an average of approximately 199 responses from each respondent per year. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Our Web-based Color Certification information system allows submitters to request color certification online, follow their submissions through the process, and obtain information on

account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hard-copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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